

Claims 1-3 and 6-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**.

II. Rejection of Claims 1-3 and 6-8 Under 35 U.S.C. § 101

The Action first rejects claims 1-3 and 6-8 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

The Action admits that contactin associated proteins (casprs) have a “specific utility” (Action at page 3), but that “Applicants have not provided any specific information regarding the specific utility of the proteins of the present invention which distinguishes them from other members of the neurexin superfamily” (Action at page 3). Applicants respectfully point out that the presently claimed sequence is clearly referred to as a contactin associated protein (see, at least, the specification at page 1, lines 9-12). Furthermore, as set forth in Applicants response filed on September 18, 2002 (“the previous response”) to the Office Action mailed on April 23, 2002 (“the previous Action”), two sequences sharing nearly 100% percent identity at the protein level with the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank), and have been annotated by third party scientists *wholly unaffiliated with Applicants* as “Homo sapiens caspr5 protein”. It is well-known in the art that caspr proteins are distinct members of the neurexin superfamily. The previous caspr proteins (caspr 2, 3 and 4) share between 42% and 63% homology with each other, but only 23% to 26% homology to neurexins (neurexin 1, 2 and 3). That Applicants claimed sequence is a caspr is further confirmed by the fact that Applicants sequence shares between 48% and 59% homology to the other caspr proteins (caspr 2, 3 and 4), but only 24% to 26% homology to the neurexin proteins (neurexin 1, 2 and 3), perfectly in line with the previously established figures. The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given these GenBank annotations, there can be no question that those skilled in the art would clearly believe that Applicants’ sequence is a contactin associated protein. As the Examiner admits that casprs have a specific utility, due to their association with “myelinated axons and potassium channels” (Action at page 3), the claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

Applicants previous response detailed a number of additional substantial and credible utilities,

including the use of the presently claimed sequence in diagnostic assays, as described in the specification, at least at page 10, lines 15-19. As described in the specification at page 15, lines 21-25, the present sequences define a coding single nucleotide polymorphism - specifically, a C/T polymorphism at position 812 of SEQ ID NO:1, which can lead to a serine or leucine residue at amino acid position 271 of SEQ ID NO:2. However, the Action states that "without knowing the functions (i.e. utility) of the polynucleotide and protein of the present invention, one cannot assess a utility for the diagnostic assays using these molecules" (Action at page 3). As the utility for the presently claimed caspr has been clearly established, above, this argument has been rendered moot. Additionally, Applicants point out for the record that the use of such polymorphisms in diagnostic assays such as forensic analysis, which is undoubtedly a "real world" utility, does not require any knowledge of the function of the polynucleotide or the encoded protein. The presence or absence of the polymorphism alone serves as the basis for distinguishing individual members of the population, which is all that a forensic analysis is designed to accomplish. It is important to note that the presence of more useful polymorphic markers for forensic analysis would not mean that the present sequences lack utility. Thus, the claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

For each of the foregoing reasons, as well as those set forth in the previous response to the previous Action, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1-3 and 6-8 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

III. Rejection of Claims 1-3 and 6-8 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-3 and 6-8 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-3 have been shown to have "a specific, substantial, and credible utility", as detailed in section II above, the present rejection of claims 1-3 and 6-8 under 35 U.S.C. § 112, first paragraph, cannot stand.

For each of the foregoing reasons, as well as those set forth in the previous response to the